



# Design & Management of Field Studies in Epidemiology

**BE-9075**

**3 Graduate Credit Hours**

**Tuesdays: 1:00 – 3:50 PM**

**Rm. 121 Kettering Lab**

## **Course Professors:**

### **Patrick Ryan, PhD, MS**

Professor

Departments of Pediatrics and Environmental Health

Division of Biostatistics and Epidemiology

Cincinnati Children's Hospital Medical Center

University of Cincinnati, College of Medicine

**Office:** (513) 803-4704

[patrick.ryan@cchmc.org](mailto:patrick.ryan@cchmc.org)

**Office Hours:** Upon request, CCHMC T10.384

### **Kelly Brunst, PhD**

Assistant Professor

Department of Environmental Health

University of Cincinnati, College of Medicine

**Office:** (513) 558-1723

[kelly.brunst@uc.edu](mailto:kelly.brunst@uc.edu)

**Office Hours:** Upon request, Kettering, Rm. 140

If in need of an urgent response, please call one of us.

## **Course Description:**

This course provides students with the opportunity to acquire knowledge and skills in the design and conduct of clinical and field based research. The course will focus on the grant-writing process including formulating a study hypothesis, writing strong specific aims, the significance and innovation of your study, and developing and conducting the study methods including designing questionnaires, survey sampling, and sample size determination. Students will also learn the multiple components of an NIH 'R' grant application, the NIH grant review process, and how to evaluate research proposals.

## **Student Learning Outcomes:**

The course objectives include the following:

- acquire knowledge and skills in formulating a research question,

- learn to critique and interpret scientific literature and research proposals
- develop a hypothesis and specific aims
- create an appropriate plan of investigation
- write a mini research proposal
- learn the NIH approach to evaluate research proposals

Class sessions will address core issues relevant to each step in the research process. You should learn to write in a crisp, clear and succinct manner. Attention should be given to the following:

- a thorough review of the literature
- using the optimum study design
- understanding the assumptions made when calculating sample size
- utilizing sampling methodologies
- characterizing independent and dependent variables
- measuring reliability and validity
- understanding the NIH process for critiquing research.

### **Course Texts:**

- Hulley, S.B., Cummings, S.R., et al. Designing Clinical Research. 4<sup>th</sup> Ed. 2013. Lippincott Williams and Wilkins.  
**Older additions are similar.**
- Optional: Strunk, W. and White, E.B. The Elements of Style. 4<sup>th</sup> Ed. 2000. (~\$12.00)  
You are also evaluated on written style including paragraph and sentence structure.  
**Cheaper texts available at [www.amazon.com](http://www.amazon.com)**
- Course pack. All supplemental reading and handouts have been combined. This can be found online through Canvas.

### **Course Requirements:**

1. Weekly reading assignments, class attendance, and class participation. Much of the subtle finer points of research proposal development will come from the oral exchange in class. Your learning will be proportional to your participation. If you are on call please put phone/pagers on vibrate.
2. Submission of homework assignments to Canvas. Homework is designed to provide you with ongoing feedback but please be respectful and make sure it is turned in on time. Late homework assignments are subject to a 10% reduction in your grade for that assignment.
3. In class peer review of classmates' homework assignments.
4. Evaluation of a classmate's research proposal using the NIH peer review method.
5. Submission of NIH R21-like formatted proposal (details attached).
  - **Peer Review**  
Students will be required to provide thoughtful, constructive criticism on classmates' homework assignments. Peer review sessions will be completed during class time. Students are required to bring a hardcopy of their homework to class for these sessions.
  - **Presentation**  
Students will prepare a 10-minute presentation of their research proposal and present it during class as if they were presenting at a national/international conference. The presentation should include the following elements: background, significance, hypothesis, specific aims, and methods.
  - **NIH R21-like Proposal**  
Details provided on following pages.
  - **NIH Peer Review Critique**  
On the last day of class, everyone will turn in their final proposal. Each student will be randomly assigned someone else's research proposal just as if you are a member of a study section. Your score will be based on the critique of your fellow student's proposal. The review and score given by you, the reviewer, will only be used to evaluate *your* knowledge and skill for evaluating another's research and writing skills.

- **It is very important that you arrive to class on time during this in-class review session.** We will be randomly assigning each proposal to another student, and the late arriver’s proposal will be given to someone who has already started the review process of another proposal – making them an unhappy reviewer, right off the bat!
- **If you are unable to be at class on this date or due to other demands cannot complete your proposal on time then it is suggested that you drop this class.**

**Course Grading:**

Homework Assignments	10% (80 points)
Presentation	15% (120 points)
NIH Peer Review Critique	15% (120 points)
NIH R21 Proposal	60% (480 points)
	<hr/>
	800 points

**Course Grading Scale:**

<b>A</b> 100-95	<b>B-</b> 84-80	<b>F</b> 69-below
<b>A-</b> 94-90	<b>C</b> 79-75	
<b>B</b> 89-85	<b>C-</b> 74-70	

**Canvas:**

The Design & Management of Field Studies course uses Canvas (learning management system) to provide student-centered online learning that will enhance the teaching and learning process. If you are not familiar with this tool or have questions, please visit [CET&L Canvas Resources for Students](#).

**Course Communication:**

University policy requires that the email set up in Canvas is the primary means of communication. It is advisable that you use your UC email for this purpose and that you check it often. If you choose to change your email in Canvas to a non-UC email it is your responsibility to ensure you check it frequently.

**Course & Grading Policies:**

- 1. Course Contract:** Upon officially registering for the course, the student assumes responsibility for understanding and complying with the entire contents of the course syllabus. It is the student’s responsibility to raise questions or concerns directly with the instructor. The course instructor reserves the right to change, modify, add or delete any class assignment, reading, or activity at any time. Such changes will be made at the earliest possible time
- 2. Academic Code of Conduct:** Academic misconduct or dishonesty is defined in the University of Cincinnati Student Code of Conduct. Academic misconduct includes, but is not limited to: acts of cheating, plagiarism, falsification, and misappropriation of credit. The Student Code of Conduct defines behavior expected of all University of Cincinnati students. It is each student’s responsibility to know and comply with the University’s Student Code of

Conduct. Disciplinary procedures are explained in a step-by-step manner, and the procedures for appeal of decisions are stated. (see: [UC's Student Code of Conduct](#))

**Plagiarism is defined as:**

- Submitting another's published or unpublished work in whole, in part, or in paraphrase, as one's own without fully and properly crediting the author with footnotes, quotation marks, citations, or bibliographic reference.
- Submitting as one's own original work, material obtained from an individual, agency, or the internet without reference to the person, agency or webpage as the source of the material.
- Submitting as one's own original work material that has been produced through unacknowledged collaboration with others without release in writing from collaborators.
- Submitting one's own previously written or oral work without modification and instructor permission.

Plagiarism will not be tolerated and according to the Student Code of Conduct ([https://www.uc.edu/conduct/Code\\_of\\_Conduct.html](https://www.uc.edu/conduct/Code_of_Conduct.html)), may result in the following consequences:

- Formal report of academic misconduct.
  - Reduced or failing grade on the exercise.
  - Reduced or failing grade for the course.
  - Recommendation to the College Hearing Panel/Dean/Provost for probation, suspension, or dismissal.
- 3. Disability:** Students with disabilities who need academic accommodations or other specialized services while attending the University of Cincinnati will receive reasonable accommodations to meet their individual needs as well as advocacy assistance on disability-related issues. Students requiring special accommodation must register with the Disability Services Office. [UC's Disability Services Office](#).
  - 4. Counseling Services, Clifton Campus:** Students have access to counseling and mental health care through the University Health Services (UHS), which can provide both psychotherapy and psychiatric services. In addition, Counseling and Psychological Services (CAPS) can provide professional counseling upon request; students may receive five free counseling sessions through CAPS without insurance. Students are encouraged to seek assistance for anxiety, depression, trauma/assault, adjustment to college life, interpersonal/relational difficulty, sexuality, family conflict, grief and loss, disordered eating and body image, alcohol and substance abuse, anger management, identity development and issues related to diversity, concerns associated with sexual orientation and spirituality concerns, as well as any other issue of concerns. After hours, students may call UHS at 513-556-2564 or CAPS Cares at 513-556-0648. For urgent physician consultation after-hours students may call 513-584-7777. ***Your instructor (Dr. Kelly Brunst) has been identified as a Mental Health Champion for the University of Cincinnati in the College of Medicine. Do not hesitate to reach out to her if you have concerns or just want to talk.***
  - 5. Title IX:** Title IX is a federal civil rights law that prohibits discrimination on the basis of your actual or perceived sex, gender, gender identity, gender expression, or sexual orientation. Title IX also covers sexual violence, dating or domestic violence, and stalking. If you disclose a Title IX issue to me, I am required to forward that information to the Title IX Office. They will follow up with you about how the University can take steps to address the impact on you and the community and make you aware of your rights and resources. Their priority is to make sure you are safe and successful here. You are not required to talk with the Title IX Office. If you would like to make a report of sex or gender-based discrimination, harassment or violence, or if you would like to know more about your rights and resources on campus, you can consult [UC's webpage for Title IX](#) or contact the office at 556-3349.
  - 6. Weather Related Protocol:** When inclement weather threatens the safety of the University of Cincinnati community, the Senior Vice President for Administration and Finance may invoke University Rule [3361: 10-55-01](#) and declare an emergency closing. College of Medicine Students: Graduate Students – follow all University snow policies and procedures. All classes and exams are canceled when the university has closed. On days when the University delays opening, classes and exams will resume at the hour that the University reopens if this is at or before 3 pm. **IF there is a closure during our regular class meeting time, we will NOT meet for class that day.**

**Research is a creative process, both an art and a science. Enjoy!**

## **Proposal Submission Outline**

Use this as a guide to submit your final proposal. It is based on NIH guidelines, but revised for this course. **All bold, underlined terms are required, and will be used to determine your proposal grade.** Refer to your syllabus and class lectures, and adjust to suit your proposal. You will also be graded on writing style and organization. The proposal that you turn in will be based on the NIH R21 award guidelines with some exceptions noted below. The instructions below are what are required for this class - be sure to follow these guidelines carefully. Each numbered section below should start on a new page. We will follow NIH requirements for margins and font (11 pt Arial font, single-spaced, ½" margins).

### 1. NIH Face Page 1 (**title**, your name and contact)

### 2. **Project Summary (Abstract)** (31 lines)

- Summarize your proposed research
- Briefly provide background/rationale, outline the hypothesis and specific aims, and research design
- Briefly provide information on significance and innovation

### 3. **Project Narrative**

- 2-3 sentences to describe the relevance of the research to public health
- Use easy to understand language appropriate for lay audience

### 4. **NIH Biosketch**

- Please make sure to include the personal statement section tailored to your proposal
- Make sure publications are up to-date and include PMID numbers

### 5. **Specific Aims Page (1 Page Limit)**

- State concisely the goals of the proposed research and summarize the expected results, including the impact that the results of the proposed research will exert on the research field(s) involved.
- List succinctly the specific objectives of the research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology.
- Use selective bolding, *italics* and/or underlining to emphasize the **hypothesis** and **specific aims**.

### 6. **Research Strategy (3 Page Limit, Single Spaced)**

The research strategy must include the following three sections (each separately labeled):

- A) Significance
- B) Innovation
- C) Approach

The entire Research Strategy may not exceed 3 single spaced pages for this class  
(NIH guidelines allow for 6 or 12 pages for R21 and R01 applications, respectively)

#### A. **Significance**

- Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses
- Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.
- Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved
- Incorporate your relevant literature review as background and supporting information in this section
- State clearly the public health significance of your proposal and once successful how your project will positively impact/improve public health

## B. Innovation

- Explain how the application challenges and seeks to shift current research or clinical practice paradigms
- Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions
- Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions

## C. Approach

- **Preliminary studies/data**. Provide a description of **Preliminary Studies** using data that **YOU** have gathered. Discuss the PD/PI's preliminary studies, data, and or experience pertinent to this application.
- A clear description of the **study design**. Describe the overall strategy, methodology, and analyses to be used to accomplish the aims of your project
- A clear description of the **study population including inclusion/exclusion criteria**
- A clear definition of **outcome and predictive variables**
- Descriptions of research tools and their **reliability/validity**, and methods to address **quality control** and **quality assurance**. Include information on how the data will be collected, analyzed, and interpreted. If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high risk aspects of the proposed work. Point out any procedures, situations, or materials, if any, that may be hazardous to personnel and precautions to be exercised.
- Include **statistical analysis**, including **sample size**
- Include a **limitations** section: description of potential **bias** – stating potential **confounders** and how these will be handled. Discuss potential problems, alternative strategies, and benchmarks/timelines for tasks to be completed to achieve the aims
- The new NIH guidelines include the following four key areas:
  - Scientific Premise
  - Scientific Rigor
  - Biological Variables
  - Key Biological and/or Chemical Resources

## 7. **Additional Requirement Material to Accompany your Grant Application (NOT part of page limitation):**

Tables/Figures and Timeline are incorporated within the 6 page Research Strategy of a NIH R21; however, for this class, we are NOT counting them towards your 3 page limit.

### A. **Figure/Tables**

### B. **Timeline**

### C. **Budget and Budget Justification**

### D. **References**

### E. **Literature review table**

**DESIGN & MANAGEMENT OF FIELD STUDIES IN EPIDEMIOLOGY CLASS SCHEDULE (subject to change)**

DATE	TOPIC	SPEAKER(S)	IN-CLASS EXERCISE	READINGS/ HOMEWORK
1/14/20	<ul style="list-style-type: none"> <li>• Class expectations</li> <li>• Research problem/question</li> <li>• How to use NIH RePORTER</li> <li>• Brainstorming your research problem, question, and purpose</li> <li>• Literature review</li> <li>• References</li> </ul>	<p>Ryan</p> <p>Kaplan</p> <p>Brunst</p>	<p>Example of 'Research Postcard'</p>	<ol style="list-style-type: none"> <li>1. Readings for next class: <ul style="list-style-type: none"> <li>• Chapters 1 &amp; 2</li> <li>• Hamada and Sitter, 2004 (in course pack)</li> <li>• Inouye and Fiellin, 2005 (in course pack)</li> <li>• Banerjee et. al., 2009 (in course pack)</li> <li>• Baker, 2015 (in course pack)</li> </ul> </li> <li>2. Go to NIH RePORTER website. Find 2-3 studies that are similar to yours; collect the abstracts, provide which NIH Institute and program officer. State how your project is unique and will expand the field. <ul style="list-style-type: none"> <li>• <b>Due 1/20/20 by 11:59pm, Canvas Assignment #1</b></li> </ul> </li> <li>3. Submit in pencil on a 4X6 index card: A) research problem, B) research question, &amp; C) research purpose. On the opposite side, create an artistic reflection of your research. <ul style="list-style-type: none"> <li>• <b>Due at beginning of next class, hardcopy</b></li> </ul> </li> </ol>
1/21/20	<ul style="list-style-type: none"> <li>• Independent (predictor) and dependent (outcome) variables</li> <li>• Writing specific aims page</li> </ul>	<p>Brunst</p> <p>Ryan</p>	<p>Identify your independent and dependent variables</p> <p>Peer review of note cards</p>	<ol style="list-style-type: none"> <li>1. Write and submit your hypothesis <u>and</u> specific aims. <ul style="list-style-type: none"> <li>• <b>Due 1/27/20, 11:59pm, Canvas Assignment #2</b></li> <li>• <b>Bring one hardcopy of hypothesis <u>and</u> specific aims to class</b></li> </ul> </li> <li>2. Readings for next class: <ul style="list-style-type: none"> <li>• Chapter 4</li> </ul> </li> </ol>
1/28/20	<ul style="list-style-type: none"> <li>• Quality Improvement (QI)</li> <li>• Significance</li> <li>• Innovation</li> <li>• Reliability and Validity</li> <li>• Rigor/Reproducibility</li> </ul>	<p>Beck</p> <p>Ryan</p> <p>Brunst</p>	<p>Hypothesis and specific aims peer review</p>	<ol style="list-style-type: none"> <li>1. Submit significance <u>and</u> innovation section <u>outlines</u>. <ul style="list-style-type: none"> <li>• <b>Due 2/3/20, 11:59pm, Canvas Assignment #3</b></li> <li>• <b>Bring one hardcopy of significance <u>and</u> innovation outlines to class</b></li> </ul> </li> <li>3. Readings for next class: <ul style="list-style-type: none"> <li>• Chapters 7 &amp; 8</li> </ul> </li> </ol>

DATE	TOPIC	SPEAKER(S)	IN-CLASS EXERCISE	READINGS/ HOMEWORK
2/4/20	<ul style="list-style-type: none"> <li>• Confounding/interaction</li> <li>• Causal Inference</li> <li>• Mediation</li> <li>• DAGs</li> </ul> <ul style="list-style-type: none"> <li>• Study Design Review</li> <li>• Study Design Figure</li> </ul>	Bowers  Brunst	Significance and innovation peer review	<ol style="list-style-type: none"> <li>1. Readings next class: <ul style="list-style-type: none"> <li>• Chapters 5 &amp; 6</li> <li>• Whitley and Ball, 2002 (in course pack)</li> <li>• Banerjee and Chaudhury, 2010 (in course pack)</li> </ul> </li> <li>2. Create and post your study design figure. <ul style="list-style-type: none"> <li>• <b>Due 2/10/20, 11:59pm, Canvas Assignment #4</b></li> <li>• <b>Bring one hardcopy of study design figure to class</b></li> </ul> </li> <li>3. Submit DAG for 1 bonus point, Due 2/10/20 11:59 pm, Canvas Extra Credit</li> </ol>
2/11/20	<ul style="list-style-type: none"> <li>• Approach <ul style="list-style-type: none"> <li>- Timeline/Milestones</li> <li>- Limitations/Alternative Approaches</li> </ul> </li> <li>• Preliminary Studies</li> </ul>	Ryan  Brunst	<p>Study design figure peer review</p> <p>Describe at least 2 sources of preliminary data for your study</p>	<ol style="list-style-type: none"> <li>1. Readings for next class: <ul style="list-style-type: none"> <li>• Chapter 13</li> </ul> </li> <li>2. Outline your approach section. <ul style="list-style-type: none"> <li>• <b>Due 2/17/20, 11:59pm, Canvas Assignment #5</b></li> <li>• <b>Bring one hardcopy of approach outline to class</b></li> </ul> </li> </ol>
2/18/20	<ul style="list-style-type: none"> <li>• Use of electronic medical records in research</li> <li>• Data Management</li> <li>• REDCap</li> </ul>	Harnett  Ittenbach  Baker	Approach outline peer review	<ol style="list-style-type: none"> <li>1. Readings for next class: <ul style="list-style-type: none"> <li>• Chapter 3</li> <li>• Harris et al., 2009 (in course pack)</li> </ul> </li> <li>2. Complete CITI Training <ul style="list-style-type: none"> <li>• Turn in completion report, (even if you have previously completed)-Make sure training is up to-date.</li> <li>• <b>Due 2/24/20, 11:59pm, Canvas Assignment #6</b></li> </ul> </li> <li>3. Become a CCTST member <a href="http://cctst.uc.edu/">http://cctst.uc.edu/</a></li> </ol>



DATE	TOPIC	SPEAKER(S)	IN-CLASS EXERCISE	READINGS/ HOMEWORK
2/25/20	<ul style="list-style-type: none"> <li>• Other submission requirements               <ul style="list-style-type: none"> <li>• Title</li> <li>• Project summary</li> <li>• Project narrative</li> <li>• Planned enrollment table</li> <li>• Human subjects</li> </ul> </li> <li>• Budget &amp; working with your budget office</li> <li>• Presentation Format</li> </ul>	<p>Brunst</p> <p>Ryan</p>		<ol style="list-style-type: none"> <li>1. Write and submit your title <u>and</u> summary           <ul style="list-style-type: none"> <li>• <b>Due 3/2/20, 11:59pm, Canvas Assignment #7</b></li> </ul> </li> <li>2. Sample size worksheet (in course pack):           <ul style="list-style-type: none"> <li>• Select and calculate the formula you think is correct</li> <li>• Write out your current hypothesis statement</li> <li>• Bring the manuscript/data used to determine your effect size</li> <li>• Bring your calculator to class next week</li> <li>• <b><u>Due at beginning of next class, hardcopy-Students who have completed the worksheet ahead of time will get priority for consultation</u></b></li> </ul> </li> <li>3. Readings for next class:           <ul style="list-style-type: none"> <li>• Chapters 5 &amp; 6</li> </ul> </li> </ol>
3/3/20	<ul style="list-style-type: none"> <li>• NIH grant peer review and guidelines for class review</li> <li>• Approaches to determine sample size power</li> <li>• Statistical analysis</li> </ul>	<p>Ryan</p> <p>Sucharew</p>	<p>Sample size calculation</p> <p>Statistical approach mini consultation</p>	<ol style="list-style-type: none"> <li>1. Readings for next class:           <ul style="list-style-type: none"> <li>• Chapters 19</li> <li>• Ferguson et. al., 2014 (in course pack)</li> <li>• How to be a Member of an R01 NIH Study Section (in course pack)</li> </ul> </li> </ol>
3/10/20	<ul style="list-style-type: none"> <li>• K Review criteria/K Panel</li> </ul>	<p>Brunst &amp; Guests</p>	<p>Peer review titles and abstracts</p>	<ol style="list-style-type: none"> <li>1. Write and submit your literature review table <u>and</u> timeline           <ul style="list-style-type: none"> <li>• <b>Due 3/23/20, 11:59pm, Canvas Assignment #8</b></li> </ul> </li> <li>2. Mock grant proposals (posted in Canvas)           <ul style="list-style-type: none"> <li>• <b>Due 4/13/20 – Bring hardcopy to class</b></li> </ul> </li> </ol> <p><b>Finalize your presentation</b> – email Rachel Meyer (meyer2rh@ucmail.uc.edu) for uploading prior to next class.</p>

DATE	TOPIC	SPEAKER(S)	IN-CLASS EXERCISE	READINGS/ HOMEWORK
<b>3/17/20</b>	<b>SPRING BREAK - NO CLASS</b>			
<b>3/24/20</b>	<ul style="list-style-type: none"> <li>• Student presentations</li> </ul>		Prepare feedback for each presentation	
<b>3/31/20</b>	<ul style="list-style-type: none"> <li>• Student Presentations</li> </ul>		Prepare feedback for each presentation	
<b>4/7/20</b>	<ul style="list-style-type: none"> <li>• Student Presentations</li> </ul>		Prepare feedback for each presentation	
<b>4/14/20</b>	<ul style="list-style-type: none"> <li>• Mock study section</li> </ul>	Ryan/Brunst		<ol style="list-style-type: none"> <li>1. Prepare for the final “exam” <ul style="list-style-type: none"> <li>• Prepare your final proposal following the guidelines outlined in the course pack/syllabus</li> <li>• <b>Hard copy due next week</b></li> <li>• Be prepared to review a peer’s proposal using the NIH review scoring criteria provided in the course pack</li> <li>• Bring several #2 pencils and an eraser to class next week</li> </ul> </li> </ol>
<b>4/21/20</b>	<ul style="list-style-type: none"> <li>• Final “exam” peer review</li> </ul>		Peer review of the full grant proposal	<ol style="list-style-type: none"> <li>1. Make sure to fill out course evaluation</li> </ol>
<b>4/28/20</b>	<p style="text-align: center;"><b>No class!</b></p> <p style="text-align: center;"><b>Relax &amp; have a great summer!</b></p>			